



Attorney's Docket No.: 01996-005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : James P. Koch

Art Unit : 3764

Serial No. : 09/400,817

Examiner : Michael A. Brown

Filed : September 22, 1999

Title : CUSTOM MOLDED CERVICAL CAP AND METHOD AND KIT FOR FORMING SAME

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Commissioner for Patents

Washington, D.C. 20231

DECLARATION OF JAMES P. KOCH, M.D.

I, Dr. James P. Koch, declare as follows:

1. I am a gynecologist with a strong interest in women's healthcare, contraceptive technology, and world population problems. I have been working on the development and clinical testing of cervical caps for the past 23 years.

2. There has long been a grievous need for an improved female barrier contraceptive. The existing female barrier contraceptive devices at the time of the invention, i.e., diaphragms, Today Sponges, the RealityTM Condom, and cervical caps, are intrusive and are difficult to use effectively. Moreover, these devices can only be kept in place for short periods of time, increasing inconvenience and the likelihood that the device will not be used or will be used improperly. As a result, when pregnancies due to user failure are included, all of these barrier devices have at least a 15-20% pregnancy rate per year (the Reality condom has a rate of 27%).

3. In the United States, at the time of Applicant's invention only a single cervical cap -- the Prentif cap -- was FDA approved for clinical use. This cap can only be left in place for a maximum of 48 hours, causing inconvenience and a high user failure rate (17%).

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

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4. While these problems have been long recognized, women have long sought a reliable, safe alternative to oral contraceptives, and cervical cap technology has long existed, the need for an improved cervical cap remained unresolved prior to the claimed invention. Attempts had been made to improve cervical cap technology, but none of these attempts made it to the consumer. For example, while the Goepp cap is custom-molded, and thus can be kept in place for long periods of time, clinical trials showed that this cap did not provide adequate protection against pregnancy.

5. The claimed invention meets this long felt but unresolved need by providing an improved female barrier contraceptive. Because the cap dome is custom-molded to substantially completely conform to the shape of the patient's cervix, the claimed cervical caps can be left in place for long periods of time, reducing the user failure rate attributable to improper insertion and removal. Because the cap can be left in place for long periods of time, it is also significantly less intrusive and more convenient to use than other female barrier devices. By including a valve, as recited in claims 1-16, the cap can be kept in place even during the patient's menstrual cycle.

6. Because the claimed caps include a rim member dimensioned to fit the patient's exocervix, the claimed cervical caps also provide a secure seal to prevent ingress of semen and other fluids into the cervix, thus providing reliable protection against both pregnancy and sexually transmitted diseases (STDs).

7. Because of the improved ease of use and the secure seal, the claimed cervical caps are expected to provide pregnancy rates much lower than those observed for conventional female barrier methods, making them a viable alternative to oral contraceptives.

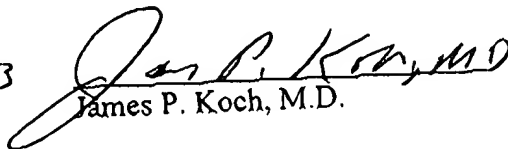
8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

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Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: January 22, 2003


James P. Koch, M.D.

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